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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/672,878	09/26/2003	Jennie P. Mather	415072000101	9515

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EXAMINER	
KIM, YUNSOO	
ART UNIT	**PAPER NUMBER**
1644	

MAIL DATE	DELIVERY MODE
10/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/672,878	MATHER ET AL.	
	Examiner	Art Unit	
	Yunsoo Kim	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,15 and 18-39* is/are pending in the application.

4a) Of the above claim(s) *7,18-27,34,36 and 37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8,9,15,28-33,35,38,39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-6, 8, 9, 15, 28-33, 35, 38 and 39 are under consideration in the instant application.

2. Upon Applicants' amendment to claim, the rejection of record withdrawn.

3. The following new rejections are necessitated by Applicants' amendments to the claims filed on 7/30/07.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out this invention.

5. Claims 1-6, 8, 9, 15, 28-33, 35, 38 and 39 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a New Matter rejection.

The specification as filed does not provide a written description for the phrase "generating a population of different monoclonal antibodies from said immunized mammal, wherein said population contains **fewer non-representative monoclonal antibodies that bind to proteins not present on said particular cell type and more monoclonal antibodies that bind to intact cell surface antigens of said particular cell type as compared to similarly sized population of different monoclonal antibodies generated from a like host mammal immunized with a plurality of like viable and intact cells whose surface are not free of serum**". Applicants have indicated the support can be found on p. 2-4, 16 of the specification. However, the specification does not provide comparison between the selective monoclonal antibody population with respect to numbers and sizes as recited.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-6, 8, 9, 15, 28-33, 35, 38 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Pat. No. 5,932,704 (IDS reference, of record) in view of U.S. Pat. No., 5,714,385 (IDS reference, newly cited).

The '704 patent teaches a method of making monoclonal antibody against a cell surface receptor. Monoclonal antibodies were generated by immunizing mice intraperitoneally with viable adult human cells expressing cell surface antigens and the preparation of cells without adjuvant (col. 3-4, in particular). Hybridomas were produced by fusing splenocytes with myeloma cells. The '704 patent teaches a method for optimization of monoclonal antibody by expanding and cloning the hybridoma colonies with positive results by limiting dilution to assure that the cells and resulting antibodies are monoclonal (col. 4, lines 40-53, in particular).

The '704 patent does not particularly teach culturing cells in serum free media as in claims 2, growing cells on a biological substrate as in claims 5-6, cells of ectodermal, endodermal or mesodermal origin as in claim 9, or using epithelial cells of embryonic or adult origin as in claims 8 and 33.

However, the '385 patent teaches a method of enhancing survival and/or proliferation of human adult and embryonic Schwann cells by culturing cells in serum free media on a laminin biological substrate (Fig 4, col. 7, lines 23-34, col. 18, col. 30 col. 32, in particular). The embryonic Schwann cells were generated from dorsal root ganglia are ectodermal origin. The '385 patent further teaches monoclonal antibodies directed toward antigens can be produced by any method which provides the production of antibody molecules by continuous cell lines in culture (col. 10, in particular).

The growth of cells in a monolayer or aggregates is an inherent property of the cells and the claims 3-4 are included in this rejection.

It would have been obvious to one of the ordinary skill in the art at the time the invention was made to substitute the human adult or embryonic Schawann cells grown in serum free media on a biological substrate taught by the '385 patent in the teachings of the '704 patent to a method for producing or optimizing monoclonal antibody population that binds cell surface antigens.

One of ordinary skill in the art would have been motivated to do so because the cells grown in serum free media in the '385 patent have increased viability and proliferation and the cells taught in the '704 patent used for immunization were viable. Therefore, one of the ordinary skill in the art would have had a reasonable expectation of success that the viable adult or embryonic Schwann cells could be utilized to immunize heterologous mammal to generate a collection of monoclonal antibodies.

From the combined teachings of references, one of the ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of the ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence to the contrary.

Applicants' arguments and the declaration of Mather filed on 7/30/07 have been fully considered but they are not persuasive.

Applicants argue that the showing of experimental results that would have not been expected upon merely combining the techniques of the references. The Declaration by Mather shows more production of hybridomas obtained from the mice injected with serum free cells.

As discussed above, the use of serum free media for Schwann cells enhances proliferation and viability of the cells. The human embryonic Schwann cells and human adult Schwann cells enhance survival and proliferation when cultured in serum free media on a laminin biological substrate. The production of more hybridomas obtained from the mice injected serum free cells are expected as seen in the Declaration by Mather. Applicant's declaration relied on unexpected results does not overcome clear and convincing evidence of obviousness.

8. No claims are allowable.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yunsoo Kim whose telephone number is 571-272-3176. The examiner can normally be reached on Monday thru Friday 8:30 - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Yunsoo Kim
Patent Examiner
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January 11, 2007

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